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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: March 3, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Holiday Inn Oakland Airport
500 Hegenberger Road
Oakland, CA 94621

Workgroup Members: Ken Schell, Pharm.D., Chair
John Tilley, R.Ph.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Paul Riches, Chief of Legislation/Regulation
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Purpose of the Workgroup

Dr. Schell explained that the Board of Pharmacy originally formed this workgroup at the request of the Department of Health Services, State Food and Drug Branch (FDB). The FDB is responsible for licensing California's drug manufacturers and asked the board to clarify the criteria it uses to determine when pharmacy compounding falls outside the scope of pharmacy practice. Dr. Schell also stated that it is the board's goal to identify "gaps" in pharmacy law related to compounding and to address them. The purpose of the workgroup is for the board to work with the profession to identify compounding issues, gaps in pharmacy law and to the extent possible seek solutions.

Federal Food and Drug Administration (FDA)
COMPLIANCE POLICY GUIDES – Sec. 460.200 – Pharmacy Compounding

Fred Richman and Kathy Anderson from the FDA Center for Drug Evaluation and Research participated in the workgroup discussion via telephone. They answered questions regarding the May 2002 compliance guide that was issued regarding pharmacy compounding. The document provides guidance to pharmacies and the staff of the FDA on how the FDA addresses pharmacy compounding of human drugs as a result of the decision of the Supreme Court in Thompson v. Western States Medical Center, No. 01-344, April 29, 2002.

As they indicated, the FDA generally defers to state authorities with regard to the day-to-day regulation of pharmacy compounding of human drugs. FDA recognizes that pharmacists traditionally have compounded human drugs upon receipt of a valid prescription for a patient from a licensed practitioner. This traditional activity is not the subject of the compliance guide.

What concerns the FDA are pharmacies that are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is outside the bounds of traditional pharmacy practice. FDA is concerned that some pharmacies are involved in large scale compounding that is essentially manufacturing. It was explained that while all compounded drugs are "unapproved" new drugs by FDA law, FDA recognizes the need for extemporaneous compounding, in reasonable quantities, upon a valid prescription order to meet individual patient needs and where appropriate, FDA exercises its enforcement discretion. The FDA's primary responsibilities are to protect the public health and that may be jeopardized when there is large scale pharmacy compounding. As the volume of compounding increases so does the public's exposure to potential problems. Pharmacies are not subject to the New Drug Application (NDA) process and Good Manufacturing Practices (GMPs) required of manufacturers. These requirements are important to ensure the safety and effectiveness of the drug.

Representatives from FDA stated that the agency is working on revising the guidelines and plans to have a public meeting to discuss pharmacy-compounding issues.

Overview of Pharmacy Law Related to Compounding – Application of USP 797

Supervising Inspector Dennis Ming identified the pharmacy law that regulates compounding. He stated that the proposed amendments to California Code of Regulations, title 16, sec. 1751-1751.12, were adopted by the Board of Pharmacy at its meeting in October. He stated the regulations are going through review by the Administration and should be filed with the Office of Administrative Law (OAL) in the near future. The proposed regulations govern the compounding of injectable sterile drug products.

There were questions as to how the recently approved U.S. Pharmacopeia (USP) General Chapter 797 on pharmaceutical compounding of sterile preparations affect California pharmacy practice and the pending regulations. USP Chapter 797 provides procedures and requirements for compounding preparations. It is intended to be applicable to health care institutions, pharmacies, physicians practice facilities, and other facilities where compounded sterile preparations are prepared, stored and dispensed. Many of the participants were of the opinion

that USP 797 has the same force of law and may void the board's pending regulations if the USP requirements are more restrictive.

It was explained that during the development of the proposed regulations on sterile compounding of injectable drug products, the board was unable to find any legal reference that adopted USP 797 as federal or state law. Many disagreed with this statement and offered to provide the federal and/or state law that recognizes the USP standards as law.

Identification of Compounding Issues

The workgroup identified compounding issues that they felt that the Board of Pharmacy should address. The workgroup identified the issues, classified them and then workgoup members volunteered to develop suggestions to address the issues. When developing the proposals, various references were suggested such as USP, FDA requirements and compliance guides, professional association guidelines, NABP's model laws and other states' requirements.

LAW

- Manufacturing/Compounding
- Efficacy
- OTC Compounding
- Veterinary Compounding
- Definition of Compounding
- Anticipatory Compounding
- Central Fill for Compounding
- Label on "unit of use" containers

Workgroup Members: Dan Wills, Wayne Vega, Mike Koch, Bill Blair

Quality Standards

- Non-sterile Compounding (USP 795/1075)
- Equipment Quality/Process Validation

Workgroup Members: Steve Feldman, Helen Chang, Chuck Leiter, Joe Grasela

Sterile Compounding

- Clarification of USP 797 and impact on California regulations on compounding of sterile injectable drug products
- Environmental Control of sterile compounding
- Clarification of state/federal definition of inhalation drugs, otics, and ophthalmic
- Oils/Suspensions – Appropriate Sterilization Process

Separation of Sterile vs. Non-sterile Compounding Process

Prioritization of Issues and Assignments

Dr. Schell requested that the workgroup members that volunteered to work on the various issues do so in-between meetings. It was also noted that the workgroup would not be addressing the

issue of sterile compounding of injectable drug products since the board has adopted regulations in this area. All proposals that are to be considered by the workgroup should be sent in at least two weeks before the next workgroup meeting. The proposals will then be shared with the group in advance of the meeting.

Future Meeting Dates

Dr. Schell stated that the Workgroup on Compounding Issues will meet as needed after the Licensing Committee. The dates are: June 9th (Burbank), September 22nd (Oakland) and December 1st (Burbank).

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.